

K912748 BINAX EQUATE(R) GLYCOHEMOGLOBIN 3 MINUTE TEST KITOct 31, 1991
132 days to decisionK912748 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k912748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 21, 1991
Decision date	Oct 31, 1991
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Binax, Inc.
Location	S. Portland, ME, US
Contact	JAMES C JACOBSEN
510(k) history	30 submissions · 30 cleared · 1986-2010

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